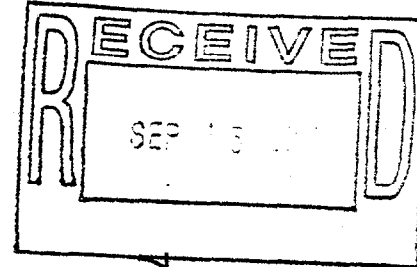


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August 30, 2000

The Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C. Street S.W.  
Washington, DC 20204



Dear Sir/Madam:

This is a notification pursuant to 21 U.S.C. 343(r)(6) that Standard Process Inc., Palmyra, Wisconsin 53156-0904, is making the following statements:

- (1) Prost-X contains acids, enzymes, and hormone precursors from bovine prostate gland to maintain the health of bone, muscle, and nerve tissues.
- (2) Prost-X contains bovine prostate Cytosol™ extract, which provides concentrated nutrients that are especially supportive to their parallel tissues in the human body. Prost-X contains a naturally occurring spreading factor that supports normal tissue development, maintenance, and repair. Prost-X contains phosphatase enzymes that promote healthy bones, muscles, and nerves.
- (3) Promotes tissue development, maintenance and repair.
- (4) Enzymes contained in Prost-X have been observed in tissue development of the lung, eye, kidney, and embryonic tissues. Increased activity of these enzymes has been associated with supporting various stages of embryonic development. Strong evidence suggests that these enzymes are responsible for enabling connective tissue to form capillaries, tendons, skeleton and muscle. These enzymes are also thought to support the normal turnover and remodeling of tissues, promoting systematic tissue maintenance. These enzymes play a fundamental role in supporting the blood supply and redistributing body nutrients to facilitate normal tissue restoration.
- (5) Supports reproductive function.
- (6) Supports healthy cellular function.

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*Whole Food Supplements*

- (7) Prost-X contains a spreading factor that is known to cause tissue to be more permeable. This enzyme supports proper cellular function by stimulating capillary formation that allows important body nutrients to reach cells and tissues.
- (8) Contains a unique blend of nutrients from ingredients like prostate Cytosol™ extract and Tillandsia to help support prostate health, reproductive function, and proper calcium metabolism.
- (9) Contains unique glandular materials of Cytosol™ extract that support the corresponding organs in humans.

These statements are made for a dietary supplement containing a proprietary blend of Tillandsia usneoides, calcium glycerophosphate, and bovine prostate Cytosol™ extract. Other ingredients include gelatin, honey, water, natural colors, and calcium stearate. The name of the product is Prost-X™.

The information contained herein is accurate and Standard Process Inc. has substantiation that the statements are truthful and not misleading.

Sincerely yours,

Ann Holden  
Standard Process Inc.

